

Stelara[®] (ustekinumab) – Expanded indication

- On October 13, 2017, [Janssen announced](#) the FDA approval of [Stelara \(ustekinumab\)](#) for adolescent patients (12 years or older) with moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy.
 - Previously, Stelara was indicated only for adult patients for this indication.
- Stelara is also indicated for adult patients with active psoriatic arthritis, alone or in combination with [methotrexate](#); and moderately to severely active Crohn's disease who have failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker or failed or were intolerant to treatment with one or more TNF blockers.
- The expanded indication for Stelara was based on a placebo-controlled study conducted in 110 adolescent patients aged 12 – 17 years with plaque psoriasis, who were candidates for phototherapy or systemic therapy and whose disease was inadequately controlled by topical therapy. The endpoints were the proportion of patients who achieved a Physician's Global Assessment (PGA) score of cleared (0) or minimal (1), Psoriasis Area and Severity Index (PASI) 75, and PASI 90 at week 12.
 - The PGA score was achieved in 69.4% of Stelara-treated patients vs. 5.4% of placebo-treated patients.
 - The PASI 75 was achieved in 80.6% of Stelara-treated patients vs. 10.8% of placebo-treated patients.
 - The PASI 90 responders were 61% of Stelara-treated patients vs. 5.4% of placebo-treated patients.
- The recommended dosage of Stelara in adolescent patients for plaque psoriasis is weight based dosing given subcutaneously at weeks 0 and 4, then every 12 weeks thereafter as follows:

Body Weight at Time of Dosing	Dose
< 60 kg	0.75 mg/kg
60 kg – 100 kg	45 mg
> 100 kg	90 mg

- Consult Stelara's drug label for injection volumes of Stelara 45 mg/0.5mL single-dose vials for adolescent patients weighing < 60 kg and for dosing for adult patients for all indications.
- In adolescent patients, it is recommended that Stelara be administered by a health care provider.